UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,403	09/17/2003	Karen Theel	021756-002300US	8953

51206 7590 09/30/2008

TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
MEYERS, MATTHEW S	

ART UNIT	PAPER NUMBER
3689	

MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,403	THEEL ET AL.	
	Examiner	Art Unit	
	MATTHEW S. MEYERS	3689	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 27-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 27-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's communication on 7/25/08, wherein claims 1-12 and 27-35 are currently pending.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/25/08 has been entered.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-12 are rejected under 35 U.S.C. 101 because In order for a method to be considered a "process" under §101, a claimed process must either: (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials). Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972). If neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and is non-statutory subject matter. With respect to

claims 1-12, the claim language does not include the required tie or transformation and thus is directed to nonstatutory subject matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-2, 4-5, 8-12, 27-28, 30 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stability Lab Information Manager (hereinafter referred to as "SLIM") in view of Stability System 2000, as retrieved from the way back machine, http://web.archive.org/web/20020810103720/www.stabilitysystem.com/index1.htm (Hereinafter referred to as Stability).

8. With respect to claims 1 and 27, SLIM discloses a method and a tangible computer readable medium storing a set of instructions for managing a stability study, comprising:

a. receiving input via the one or more interfaces indicative of a set of requirements for a first stability study (interpreted to be disclosed by the Lab Work Request data entry forms, Page 4 Line 1);

b. displaying one or more interfaces that enable a user to create workflows associated with stages of stability studies, a workflow including information configured to prompt a user to perform one or more actions that need to be taken during a stage associated with a stability study in order to fulfill requirements specified for the stability study (interpreted to be disclosed by the Lab Work Request data entry forms, Page 4 Line 1 and Stability, Page 1 “most database fields can have preset terms to facilitate information entry and terminology standardization to assist in the database query”);

c. receiving input via the one or more interfaces indicative of a set of workflows associated with a plurality of stages of the first stability study, each workflow specifying a set of actions that need to be taken during each stage in the plurality of stages of the first stability study (interpreted to be disclosed by the Lab Work Request data entry forms, Page 4 Line 1 and Stability, Page 1 “most database fields can have preset terms to facilitate information entry and terminology standardization to assist in the database query”);

d. displaying one or more interfaces that enable a user to specify business rules for the stability study (interpreted to be disclosed by the Lab Work Request data entry forms, Page 4 Line 1);

e. receiving input via the one or more interfaces indicative of a set of business rules for the first stability study (interpreted to be disclosed by the Lab Work Request data entry forms, Page 4 Line 1);

f. generating one or more interfaces for the first stability study based on the set of requirements that need to be fulfilled for the first stability study, the set of workflows associated with the plurality of stages of the first stability study, and the set of business rules, wherein the one or more interfaces define the set of requirements for the stability study (interpreted to be disclosed by the Lab Work Request data entry forms, Page 4 Line 1 and Stability, Page 1 “most database fields can have preset terms to facilitate information entry and terminology standardization to assist in the database query”;)

g. displaying the one or more interfaces (interpreted to be the displaying of the Lab Work Request data entry forms on screen, Page 4 Line 1)

h. receiving input information via the one or more interfaces; the received input information for fulfilling the requirements (interpreted to be the feature of the Lab Work Request forms allowing the user to enter results, Page 4 Line 1)

i. SLIM discloses all the above limitations, additionally SLIM discloses Lab Work Request data entry forms (Page 4 Line 1). Slim does not explicitly disclose displaying one or more interfaces that enable a user to create stability studies by

specifying requirements that need to be fulfilled for the stability studies. Stability teaches a database field definition which can be customized to meet the user's requirement and completely menu-driven and user friendly features which allow it to conduct its stability testing program (Stability, Page 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the Stability Lab Information Manager of SLIM with the Stability testing program of Stability in order to develop and manage a stability testing program, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

j. SLIM discloses all the above limitations, additionally SLIM is interpreted to disclose a verification of data entered into the Lab Work Request forms to determine whether the input information is acceptable, Page 4 Line 1 and Page 5 line 4). However, SLIM does not explicitly discloses wherein validating the received input information against the set of business rules for the stability study to determine whether the input information is acceptable. Stability teaches on-screen checking for out-of-specification data (Stability, Page 1) and a Comprehensive validation script and test results are provided to the users with specific examples for performing the software validation. It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the Stability Lab Information Manager of SLIM with the Stability testing program of Stability in order to develop and manage a stability testing program which validates the received input information against the set of business rules

for the stability study to determine whether the input information is acceptable, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

k. SLIM and Stability disclose all the above limitations, but neither SLIM nor Stability explicitly discloses provides and provides or receives a first, second, third, and forth interface repeatedly as claimed by applicant. However, it would have been obvious to one of ordinary skill and creativity at the time of the invention to have repeated the process as claimed in SLIM for a first, second, third, or forth interface as claimed. Simply repeating the providing and receiving steps with a new input does not make the present application patentably distinct from SLIM since SLIM is capable of incorporating any number of variables through its use of Excel™ (SLIM, Page 2). Additionally, Stability allows the database field definition to be customized to meet the user's requirement which would allow for a first, second, third, or fourth interface as described above.

9. With respect to claims 2 and 28 SLIM discloses: if the input information is acceptable, storing the input information (interpreted to be inherently disclosed as the reference discloses the ability to enter data, from which reports are generated and the selected data from the reports may be saved, Page 4 Line 1 and Page 3 lines 9 – 10 and Stability, Page 2, "audit trail capability which tells you who did what and for what reason").

10. With respect to claim 4 and 30 SLIM discloses: determining whether approval from a user is needed for the input information based on the set of workflow (interpreted

to be the disclosure that data passes through a approval state, inherently disclosing a determination that approval from a user is necessary, Page 5 line 4).

11. With respect to claim 5 and 31 SLIM discloses receiving an indication of approval from the user; and storing the indication(interpreted to be the disclosure that data passes through a approval state, inherently disclosing receiving indication of the approval from the user, Page 5 line 4; storing the indication interpreted to be disclosed by the feature of all changes being event logged, Page 12 lines 2 -4).

12. With respect to claim 8 and SLIM discloses the one or more forth interfaces include an interface for a stage in a plurality of stages in the stability study (interpreted to be taught by the disclosure of the ability to add a test to a protocol, implying that a plurality of tests, i.e. stages, may be part of a protocol, i.e. stability study, Page 5 lines 2 - 3).

13. With respect to claim 9 SLIM discloses the plurality of stages comprise at least two of a stability study setup criteria, stability study planning criteria, initial sampling and testing criteria, stability study launch criteria, stability study testing criteria, and stability study evaluation criteria (interpreted to be the disclosure of assigning multiple storage dates for different storage conditions for a single study and calculation of number of units needed for each storage condition, Page 9 lines 2 - 3; and the creation of product-specific or test-specific schedules, Page 10 line 1).

14. With respect to claim 10 SLIM discloses outputting information summarizing the first stability study (interpreted to be the automatic and unattended HTML report generation, Page 3 line 3).

15. With respect to claim 11 SLIM discloses determining a result of the stability study (interpreted to be inherently disclosed as the reference provides for data results to be subject to change by a user, and hence a determination of the result of the stability study must, occur, Page 12 lines 3- 4).

16. With respect to claim 12 SLIM discloses the result is inputted by a user (interpreted to be the disclosure that data results may be changed, Page 12 lines 3 -4).

17. With respect to claim 34, SLIM discloses a system for managing stability studies, the system comprising: a first interface configured to enable a user to create stability studies by specifying requirements that need to be fulfilled for stability studies, workflows associated with the stages of the stability studies, and business rules for stability studies; a database configured to store information associated with the requirements, the workflows, and the business rules for stability studies, wherein a workflow includes information configured to prompt a user to perform one or more actions that need to be taken during a stage associated with a stability study in order to fulfill requirements specified for the stability study; a stage selector configured to select a stage of a stability study and to determine from the database one or more requirements for the selected stage; a stage information manager configured to receive the one or more requirements from the stage selector, to generate a second interface that defines the one or more requirements for the selected stage that need to be fulfilled, and to generate a third interface indicative of information on actions associated with the selected stage that need to be performed; a stage information processor configured to receive input via the second and third interfaces and to validate the input

against business rules associated with the selected stage to determine whether the input is acceptable (interpreted to be the disclosure of assigning multiple storage dates for different storage conditions for a single study and calculation of number of units needed for each storage condition, Page 9 lines 2 - 3; and the creation of product-specific or test-specific schedules, Page 10 line 1).

l. SLIM discloses all the above limitations, additionally SLIM discloses Lab Work Request data entry forms (Page 4 Line 1). Slim does not explicitly disclose displaying one or more interfaces that enable a user to create stability studies by specifying requirements that need to be fulfilled for the stability studies. Stability teaches a database field definition which can be customized to meet the user's requirement and completely menu-driven and user friendly features which allow it to conduct its stability testing program (Stability, Page 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the Stability Lab Information Manager of SLIM with the Stability testing program of Stability in order to develop and manage a stability testing program, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

m. SLIM discloses all the above limitations, additionally SLIM is interpreted to disclose a verification of data entered into the Lab Work Request forms to determine whether the input information is acceptable, Page 4 Line 1 and Page 5 line 4). However, SLIM does not explicitly discloses wherein validating the received input information against the set of business rules for the stability study

to determine whether the input information is acceptable. Stability teaches on-screen checking for out-of-specification data (Stability, Page 1) and a Comprehensive validation script and test results are provided to the users with specific examples for performing the software validation. It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the Stability Lab Information Manager of SLIM with the Stability testing program of Stability in order to develop and manage a stability testing program which validates the received input information against the set of business rules for the stability study to determine whether the input information is acceptable, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

n. SLIM and Stability disclose all the above limitations, but neither SLIM nor Stability explicitly discloses provides and provides or receives a first, second, third, and forth interface repeatedly as claimed by applicant. However, it would have been obvious to one of ordinary skill and creativity at the time of the invention to have repeated the process as claimed in SLIM for a first, second, third, or forth interface as claimed. Simply repeating the providing and receiving steps with a new input does not make the present application patentably distinct from SLIM since SLIM is capable of incorporating any number of variables through its use of Excel™ (SLIM, Page 2). Additionally, Stability allows the database field definition to be customized to meet the user's requirement which would allow for a first, second, third, or fourth interface as described above.

18. With respect to claim 35, SLIM discloses the system of claim 34 wherein the first interface is further configured to enable the user to create a specification for a first stability study as an overlay using a specification for a second stability study as a base (SLIM, Page 3, lines 7-8).

19. **Claims 3 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over SLIM in view of Stability as applied to claims 1 and 27 and in view of Strong US 6167523.

20. SLIM discloses determining whether the set of requirements for the stability study have been completed (interpreted to be the disclosure of data passing through draft, entry, verification and approval states, Page 5 line 4). SLIM does not disclose if the set of requirements have not been completed, outputting one or more fifth interfaces requesting additional input information for the requirements in the set of requirements that have not been completed. Strong discloses a method where if the requirements have not been completed (interpreted to be the teaching of validation of data entered into a form, and if data is determined to be invalid, providing to the user a message identifying the specific fields that include invalid data, C3 lines 36 - 43), outputting an interface for additional input information for the requirements that have not been completed (interpreted to be the method of resubmission of data from the user after an error message is sent indicating invalid data, C10 lines 45- 49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the features of Strong and the method of SLIM in order to provide a more

efficient computer implemented method to verify if the requirements for a stability study have been satisfied.

21. **Claims 6, 7, 32 and 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over SLIM in view of Stability as applied to claims 1 and 27 in view of Hughes et al. US Pub. 20020133395 (hereinafter referred to as "Hughes").

1. With respect to claim 6 and 32, SLIM does not disclose wherein the indication comprises at least one of an electronic signature and captured signature. Hughes discloses the use of an electronic signature to indicate approval by a user of data, and further discloses that electronic signature may include signature recognition, interpreted to be captured signature (Para 0059). Therefore, it would have been obvious to one of SLIM in light of the requirements imposed by 21 CFR Part 11 in regards to the use of electronic signatures for verification of electronic records submitted to the Food and Drug Administration.

2. With respect to claim 7 and 33, SLIM discloses receiving an indication from the user of approval, and thereby inherently disapproval (interpreted to be inherently disclosed as the references provides for result entry, verification and approval, Page 4 line 1 and Page 5 lines 1 - 4). SLIM does not disclose determining requirements that need to be completed for approval; and outputting one or more fifth interfaces defining the determined requirements. Hughes discloses determining requirements that need to be completed for approval (interpreted to be the comments attached by the reviewer, Fig. 1 and Para 0059), outputting one or more fifth interfaces defining the determined requirements that need to be completed for approval (interpreted to be the electronic

approver screen 90 in Fig. 5 and described in Para 0059). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the method of determining requirements that need to be completed for approval and outputting an interface needed to complete the determined requirements as disclosed by Hughes in the computer implemented method of SLIM, for the advantage of providing a more efficient and computer implemented method of determining requirements needed for approval and outputting an interface to complete the determined requirements.

Response to Arguments

22. Applicant's arguments filed 7/25/08 have been fully considered but they are not persuasive. Applicant's arguments have been addressed with the Office Action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW S. MEYERS whose telephone number is (571)272-7943. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jan Mooneyham can be reached on (571) 272-6805. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew S Meyers/
Examiner, Art Unit 3689

/Janice A. Mooneyham/
Supervisory Patent Examiner, Art Unit 3689